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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FOX, DAVID T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,388	GRESSEL ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-22* is/are pending in the application.

4a) Of the above claim(s) *9-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8 and 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/889,737.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 January 2008 has been entered.

The objection to the specification has been overcome by Applicant's amendment of 30 January 2008.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 4-22 are pending. Claims 9-16 are withdrawn as being drawn to a non-elected group. Claims 1, 4-8 and 17-22 are examined in the following Office action.

Claim Objections

Claims 1 and 19 are objected to for containing the following typographical errors:

In claims 1 and 19, lines 5-6, the commas after "engineered" before "mitigating" should be deleted.

Indefiniteness

Claims 6, 8, 18 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 8 are indefinite for failing to further limit claim 1 on which they depend. The "shrunken seed mutation" of claim 6, and the "modified lignin" of claim 8, do not appear to further limit the categories of mitigating or advantageous traits, respectively, recited in claim 1.

Claims 18 and 20 are indefinite in their recitation of "selected from the group consisting of … or" which employs improper Markush terminology per MPEP 2173.05(h). Replacement of "or" with ---and--- would obviate this rejection.

Claims 21-22 are indefinite in their recitation of "herbicide resistance is a *ahas* ^{R}", "dwarfism is a delta *gai"* and "shattering is a *shatterproof*" gene; which is confusing in equating traits with the genes that confer the traits. The following amendments would obviate this rejection:

In claim 21, insert ---conferred by--- after "resistance is a".

In claim 22, insert ---conferred by--- after "dwarfism is a" and "shattering is a".

All claim amendments should comply with 37 CFR 1.121(c).

Written Description

Claims 1, 4-8 and 17-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to constructs comprising a multitude of genes of a multitude of sequences and from a multitude of sources, encoding proteins (or other

products such as antisense RNA or ribozymes) of a multitude of sequences and from a multitude of sources, conferring "mitigating genetic traits" which are deleterious to weeds, including abolished secondary dormancy, uniform or delayed ripening, anti-shattering, dwarfism, seed stalk bolting, seed coat defects facilitating uniform germination, root storage promotion, biennial growth, or non-flowering; but which mitigating traits are "benign or advantageous when expressed in the commercially cultivated crop" (see, e.g., page 51 of the specification, lines 14-17). The claims are also drawn to methods of using these constructs to transform plants.

Moreover, the claims are broadly drawn to constructs comprising a multitude of genes of a multitude of sequences and from a multitude of sources, encoding proteins (or other products) which confer advantageous traits such as "high productivity, modified agronomic quality, [and] enhanced yield".

In contrast, the specification provides no guidance regarding the isolation of any protein (or other gene product) from any source or of any sequence which could confer any of the above "mitigating" traits. The single exemplified dwarfism trait was deleterious to the cultivated crop, as discussed below. Furthermore, no guidance is presented in the specification regarding the isolation or characterization of any gene encoding any of the above putative proteins or gene products. Moreover, no guidance has been provided regarding the identification or isolation of single genes which confer the above-mentioned advantageous traits, wherein said single genes could be included on a genetic construct linked to a gene conferring a mitigating trait.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP, Eighth Edition, Section 2163, page 174 of Chapter 2100 of the September 2007 revision, column 1, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Applicant's arguments filed 30 January 2008 have been fully considered but they are not persuasive. Applicant urges that the Examiner has misunderstood the examples in the specification, so that the dwarf characteristic is truly a mitigating trait. Applicant urges that the planting of the transgenic cultivated crop in orderly rows represents cultivated crop conditions, wherein the transgenic plants out-performed the wild-type plants. Applicant further urges that numerous examples of sequences which could confer mitigating traits have been provided in the specification.

The Examiner maintains that the planting of transgenic cultivated crops randomly interspersed with wild-type plants also simulates cultivated field conditions when weeds

are present, since weeds are not planted in orderly rows. Under such conditions, the transgenic crop plants had lower fitness and in many cases did not produce seed, both of which traits were deleterious to the crop plant. Furthermore, the claims are not limited to dwarfing as the mitigating characteristic.

Regarding the suggested mitigating genes in the specification, they are drawn to protein-encoding sequences, which the claims are broadly drawn to any type of sequence which confers the trait, including antisense RNA-encoding sequences and ribozyme sequences, which have not been described. Furthermore, Applicant admits that the genes conferring some of the claimed mitigating traits, such as biennial growth, have not been isolated (see, e.g., page 31 of the specification, bottom paragraph), and so cannot be described.

Enablement

Claims 1, 4-9 and 17-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to constructs comprising a multitude of genes of a multitude of sequences and from a multitude of sources, encoding proteins (or other products such as antisense RNA or ribozymes) of a multitude of sequences and from a multitude of sources, conferring “mitigating” traits which are “benign or advantageous” to

cultivated crop plants but deleterious to weeds (see, e.g., page 51 of the specification, lines 14-17), including abolished secondary dormancy, uniform or delayed ripening, anti-shattering, dwarfism, seed stalk bolting, seed coat defects facilitating uniform germination, root storage promotion, biennial growth, or non-flowering. The claims are also drawn to methods of using these constructs to transform a multitude of plants of a multitude of species, to obtain a multitude of deleterious phenotypes in a multitude of weedy species and a multitude of benign or beneficial phenotypes in a multitude of cultivated crop species.

Moreover, the claims are broadly drawn to constructs comprising a multitude of genes of a multitude of sequences and from a multitude of sources, encoding proteins (or other products) which confer advantageous traits such as "high productivity, modified agronomic quality, [and] enhanced yield".

In contrast, the specification provides no guidance regarding the isolation of any protein (or other product) from any source or of any sequence which could confer any of the above traits. Furthermore, no guidance is presented in the specification regarding the isolation or characterization of any gene encoding any of the above putative proteins or other gene products. No guidance is presented regarding crop plant transformation and the evaluation of the putative genes to confer traits which are "benign or advantageous" to the commercially cultivated crops. Moreover, no guidance has been provided regarding the identification or isolation of single genes which confer the above-mentioned advantageous traits, wherein said single genes could be included on a genetic construct linked to a gene conferring a mitigating trait. Finally, no guidance is

provided regarding the identification of any weedy species or transformation therewith to confer a deleterious trait thereto.

Traits such as “high productivity”, “modified agronomic quality” and "enhanced yield” are conferred by multiple genetic loci, i.e. are quantitatively inherited, wherein such traits are incorporated into a desired genetic background via molecular markers. It would be impossible to closely link a single gene conferring a mitigating trait to a multitude of quantitatively inherited genes conferring the advantageous traits listed above. Furthermore, the use of molecular markers in breeding is unpredictable. Goldman et al teach that the use of molecular markers to facilitate the identification of chromosomal regions associated with quantitatively inherited traits in corn is hampered by the different linkage maps generated when different breeding lines are used as parents (see, e.g., page 909, column 2, top paragraph; paragraph bridging pages 911 and 912; paragraph bridging pages 912 and 913). In addition, inconsistent results were observed regarding the correlation of particular quantitatively inherited traits (see, e.g., Goldman et al, page 910). Moreover, quantitative traits such as oil or protein content are inversely proportional to kernel size in corn (see, e.g., Goldman et al, page 908, column 1, middle paragraph and column 2, bottom paragraph). Thus, breeding for improved nutritional quality would detrimentally affect “enhanced yield” or “high productivity”, as further evidence of the unpredictability inherent in the process.

The claimed process is further hampered by the lack of currently available isolated genes which encode any or all of the proteins involved in the pathways responsible for traits deleterious to weeds (or which modify traits in a manner which

would be deleterious), such as secondary dormancy, seed shattering and bolting (see, e.g., Gressel, 1999 Tibtech, page 365, column 1, top and fourth paragraphs, and paragraph bridging the columns).

Moreover, the unpredictability inherent in the process is demonstrated by Al-Ahmad et al (2004, Applicant submitted), who teach that *cultivated tobacco* transformation with a construct encoding gibberellic acid insensitivity conferring a dwarfing "mitigating" trait resulted in the *deleterious* effects of tobacco plant death or greatly reduced flowering (see, e.g., page 697, Abstract). In contrast, Applicant's definition of "mitigating" as "benign or advantageous when expressed in the commercially cultivated crop" was not obtained.

Furthermore, the Examiner notes that the transformed tobacco and Brassica plants obtained by Applicant did not have benign traits conferred by the mitigating genetic trait. Instead, both the transformed dwarf tobacco and the transformed dwarf Brassica were inefficient competitors with wild-type tobacco or Brassica (see, e.g., page 62 of the specification, bottom two paragraphs; and page 71, penultimate paragraph). Both homozygous transgenic tobacco and homozygous transgenic Brassica failed to produce flowers as well.

Since Brassica seeds are the harvested portion of the crop, this is particularly deleterious. Such competitively disadvantaged plants would not be able to grow well when planted in a field with vigorous weeds or when mixed with some non-transgenic seeds. Thus, Applicant has not provided any examples of crop plants transformed with a sequence conferring a truly mitigating yet benign trait.

Furthermore, what constitutes a "weed" is variable and crop-species dependent, as well as temporally-dependent. For example, Desplanque et al teach that plants of the cultivated beet species may be considered "weeds" when they are volunteers which have resulted from seed left in the field the previous season, which arose from mutations in the crop species which facilitated bolting (see, e.g., page 562, column 1 and paragraph bridging the columns).

In addition, what constitutes a trait which is deleterious to a weed (or which is benign or valuable to a crop species) will depend upon the particular crop plant species and the particular weed species, as well as fluctuating environmental stressors. Desplanque et al teach that bolting, rather than being deleterious as claimed in claim 3, is an attractive trait for weed beets and their wild relatives, since it facilitates seed propagation and introgression of valuable agronomic traits such as herbidice resistance into the weeds (see, e.g., page 566, column 2, third full paragraph; page 567, Figure 2 and column 2; page 568, column 1, top two paragraphs). Bartsch et al teach that the gene encoding the BNYVV coat protein is beneficial to the sugar beet crop species in the presence of high levels BNYVV infection, but deleterious to the crop species in the presence of low viral infection levels (see, e.g., pages 143-144; page 146, column 1, first full paragraph).

Modification of "deleterious" traits, such as seed coat-influenced uniform germination, is unpredictable, given the lack of understanding of the inheritance of such traits. Linder teaches that the weedy trait of non-uniform germination, thought to be seed coat-influenced and thus maternally inherited, was not maternally transmitted by

the weedy *Brassica rapa* when used as the female parent (see, e.g., page 1181, column 2, first full paragraph; page 1183, column 2, second full and bottom paragraphs; page 1186, column 2, first full paragraph; paragraph bridging pages 1189 and 1191). This unpredictable result was also observed by Landbo et al in the weed *Brassica campestris* (see, e.g., page 212, Table 2; page 213, paragraph bridging the columns, column 2, first and second full paragraphs; page 214, column 2, first full paragraph).

Applicant also contemplates the use of antisense RNA-encoding sequences for the introduction of mitigating traits (see, e.g., pages 75-77 of the specification). However, Applicant has provided no actual evidence of any antisense RNA-encoding gene or its successful use to confer said mitigating trait. Colliver et al demonstrate the unpredictability inherent in antisense RNA-mediated gene inhibition, in their teaching that transformation of bird's foot trefoil with a construct that was antisense to a bean chalcone synthase gene unexpectedly resulted in transformants with *increased* levels of the chalcone synthase transcripts (see, e.g., page 519, column 1, middle paragraph).

Measurement of "deleterious" traits is also unpredictable, given the effects of environment on their expression, and the possible failure of workers to evaluate plants under these conditions; and given the different expression of transgenes in different genetic backgrounds (see, e.g., Linder, page 1193, column 2, bottom paragraph).

Genetic modification of traits such as seed shattering is unpredictable, due to low heritability, high environmental influence, and the effects of transformation itself. Young teaches that seed shattering in Kleingrass is not highly heritable (see, e.g., page 1156, Abstract). Thus, attempts to either isolate the genes responsible or to modify the seed

shattering trait in either the crop species or a wild relative would appear to be difficult. Oard et al teach that seed shattering in cultivated and weedy rice species is highly environmentally influenced, as well as being influenced by the genetic background of the plant, and that the act of transformation with a gene not involved in shattering may still affect the shattering trait (see, e.g., page 14, paragraph bridging the columns, column 2, first full paragraph; page 15, paragraph bridging the columns and Table 1; page 19, column 2, bottom paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify, isolate and evaluate a multitude of genes encoding non-exemplified gene products such as antisense RNA and/or conferring benign or valuable traits to a multitude of cultivated crop species transformed therewith, but conferring deleterious traits to a multitude of weedy species transformed therewith. Undue experimentation would have also been required to identify and isolate single genes conferring quantitative traits such as “high productivity, modified agronomic quality, and enhanced yield”, wherein such single genes would have been required for the tight linkage of these advantageous traits to genes conferring mitigating traits.

Applicant's arguments filed 30 January 2008 have been fully considered but they are not persuasive. Applicant urges that the Examiner has misconstrued the experimental results in the specification, as discussed above. The Examiner maintains that he has not misinterpreted the results of using a dwarfism gene, as discussed above. Regarding the remaining examples in the specification, Examples 3-5 are

prophetic and insufficient to rebut the Examiner's evidence of unpredictability. In particular, Examples 3 and 5 rely upon antisense RNA-encoding constructs, which the Examiner has deemed unpredictable as stated above.

Anticipation

Claims 1 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (U.S. Patent 5,948,956 filed 16 October 1997).

The claims are drawn to methods for transforming cultivated crop plants with a first gene encoding herbicide resistance and a second gene encoding male sterility or dwarfism, wherein the first and second gene are tightly linked with a genetic distance of no greater than 10 centimorgans from each other.

Lee et al teach methods for transforming cultivated turfgrass plants with a first gene encoding herbicide resistance and a second gene encoding male sterility or dwarfism, wherein the two genes may be on the same "transforming DNA", and wherein transgenic turfgrass plants comprising a combination of genes conferring herbicide resistance and dwarfism or male sterility are claimed (see, e.g., column 6, lines 17-26; column 9, line 44 through column 11, line 44; claims 1 and 15-17). Two genes present on the same genetic construct to be introduced into a transformed plant would inherently be less than 10 centimorgans apart.

Applicant's arguments filed 30 January 2008 have been fully considered but they are not persuasive. Applicant urges that Lee et al fail to teach a genetic distance of at most 10 centimorgans, and only teach transient expression.

The Examiner maintains that Lee et al teach that the two transgenes may be placed on the same genetic construct as discussed above, and also claim whole plants as discussed above (see, e.g., claims 16-17).

Obviousness

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42326 (MOGEN INTERNATIONAL) in view of Christou et al (U.S. Patent 6,114,603 filed 27 March 1998).

The claims are drawn to sugarbeet transformation with a first gene conferring herbicide resistance and a second gene conferring antibolting, wherein the first and second gene are tightly linked with a genetic distance of no greater than 10 centimorgans from each other.

MOGEN INTERNATIONAL teach cultivated sugarbeet transformation with a trehalose-6-phosphate phosphatase (TPP) gene, wherein said gene conferred antibolting to lettuce and thus would inherently confer antibolting to the biennial sugarbeet (if evaluated over two growing seasons), wherein antibolting is desirable for directing biomass to non-reproductive harvested structures; and also suggest the use of an herbicide resistance gene such as a bialaphos resistance gene for a selectable marker, wherein the herbicide resistance gene may be linked to the TPP gene on the genetic construct (see, e.g., Figures 19 and 21-22; page 8, lines 25-27; page 9, lines 1-11; page 24, lines 3-18; page 27, lines 10-15; page 35, lines 23-27; page 61, line 18 through page 62, line 23; page 72, line 11 through page 73, line 5; and page 148, claims 81-82).

MOGEN INTERNATIONAL does not actually teach sugarbeet plants transformed with a gene conferring bialaphos resistance.

Christou et al teach sugarbeet transformation with a gene conferring bialaphos resistance (see, e.g., claims 1-3 and 8-11).

It would have been obvious to one of ordinary skill in the art to utilize the method of sugarbeet transformation with an antibolting gene as taught by MOGEN INTERNATIONAL, and to modify that method by incorporating the bialaphos resistance gene taught by Christou et al, as suggested by MOGEN INTERNATIONAL. Two genes present on the same genetic construct to be introduced into a transformed plant would inherently be less than 10 centimorgans apart.

Applicant's arguments filed 30 January 2008 have been fully considered but they are not persuasive. Applicant urges that the combined references do not teach or suggest a genetic distance of at most 10 centimorgans between the transgenes. The Examiner maintains that the two genes may be present on the same genetic construct, which would inherently result in their tight genetic linkage within Applicant's definition.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/30162 (FORBIO RESEARCH) in view of Boudet et al (U.S. Patent 5,451,514).

The claims are drawn to methods of tree transformation with a first gene conferring modified lignin and a second gene conferring tapetum-specific expression of a cytotoxic gene.

FORBIO RESEARCH teaches eucalyptus tree transformation with a gene comprising a tapetum (part of the stamen, a male flower part) – specific promoter

operably linked to a structural gene encoding the cytotoxin barnase, wherein male-sterile eucalyptus trees were produced, in order to produce more harvestable timber without diverting resources to flowers and seedlings; and also teaches that other genes conferring other agronomically useful traits may be employed (see, e.g., page 1, lines 11-17; page 2, lines 6-12; page 3, line 30 through page 4, line 3; page 4, line 17 through page 5, line 5; page 5, lines 20-21; page 8, lines 5-16; page 32, line 8 through page 37, line 12).

FORBIO RESEARCH does not teach eucalyptus transformation with a gene conferring modified lignin.

Boudet et al teach the isolation of a eucalyptus gene encoding an enzyme involved in lignin synthesis, and genetic constructs comprising the gene in antisense orientation with respect to a plant promoter, wherein eucalyptus tree transformation therewith would advantageously lead to modified or reduced lignin content for improved timber quality and paper production (see, e.g., column 1, lines 44-49; column 3, line 44 through column 4, line 25; column 5, lines 35-54; and claims 1-6 and 9-12).

It would have been obvious to one of ordinary skill in the art to utilize the method of eucalyptus transformation with a male-specific promoter operably linked to a cytotoxin gene as taught by FORBIO RESEARCH, and to modify that method by incorporating a gene modifying lignin content as taught by Boudet et al, as suggested by each reference. The combination of two transgenes utilized for the same purpose, namely the improvement of wood quality, would have been obvious to the artisan of ordinary skill. Furthermore, it would have been obvious to place both transgenes on the

same genetic construct prior to transformation, in order to save a process step. The placement of both transgenes on a single genetic construct would result in their tight linkage of no more than 10 centimorgans. Choice of available male organ-specific promoter would have been the optimization of process parameters.

Applicant's arguments filed 30 January 2008 have been fully considered but they are not persuasive. Applicant urges that the cited references do not teach the claimed tight genetic linkage between the two traits.

The Examiner maintains that the placement of two transgenes which perform the same function on a single genetic construct would have been the optimization of process parameters, within the skill level of the ordinary artisan, in the absence of evidence to the contrary, as stated above.

Claims 1, 5 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al (US 5,731,180) in view of WO 97/29123 (JOHN INNES CENTRE).

The claims are drawn to a method of plant transformation with a first transgene comprising the *ahas*^{R} gene conferring herbicide resistance, and a second gene comprising the delta-*gai* gene conferring gibberellic acid insensitivity and thereby dwarfism, wherein the two transgenes are tightly linked, and wherein the plant is either tobacco or *Brassica*.

Dietrich et al teach plant transformation with a mutated AHAS-encoding gene conferring resistance to imidzolinone herbicides, suggest the linkage of another gene of interest to the mutant *ahas* gene including a gene which confers an agronomic trait, and

further suggest the transformation of a multitude of plant species including tobacco and *Brassica* (see, e.g., Figure 6; column 1, lines 26-35; paragraph bridging columns 2 and 3; column 3, lines 13-28; column 6, lines 30-36 and 58-67; column 7, lines 1-9; and claims 1-8).

Dietrich et al do not teach plant transformation with a closely linked dwarfism gene.

JOHN INNES CENTRE teaches *Brassica* and tobacco transformation with the mutant delta-*gai* gene, and suggests the co-transformation of a marker gene including a gene encoding AHAS conferring herbicide resistance (see, e.g., page 1, bottom paragraph; page 2, top paragraph and second full paragraph; page 3; page 4, lines 1-14; page 7, lines 10-14; page 24, lines 9-22; paragraph bridging pages 25 and 26; page 26, lines 7-12 and 25-28; pages 27-28; page 29, lines 1-10; page 34, lines 12-13; page 44, bottom paragraph; page 45, lines 1-20; page 46, lines 11-14; Figures 3-4 and 6).

It would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation with a mutant *ahas* gene conferring herbicide resistance as taught by Dietrich et al, and to modify that method by incorporating *Brassica* or tobacco transformation and the mutant *gai* gene tightly linked to the *ahas* gene as taught by JOHN INNES CENTRE, as suggested by each reference. The genetic distance of 10 centimorgans or less would have been an inherent property of the construct suggested by each reference, as discussed above.

Conclusion

Claims 4, 6 and 17-18 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest either isolated genes conferring the variously recited mitigating or advantageous traits, or plant transformation with the two genes on the same genetic construct (i.e. tightly linked no more than 10 centimorgans apart).

The following subject matter would be allowable: Claims drawn to a method using the *shatterproof* gene as the mitigating construct, tightly linked no more than 10 centimorgans away from an advantageous gene which encodes a protein, wherein said advantageous gene confers a trait selected from the group consisting of herbicide resistance; disease, insect or nematode resistance; environmental stress resistance; bioremediation; expression of heterologous products and genetically modified plant products.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 28, 2008

/David T Fox/

Primary Examiner, Art Unit 1638